



**PATENT**  
Attorney Docket No. SPV-001  
(7931/2)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS: Spievack                      PATENT NO.: 6,576,265  
SERIAL NO.: 09/691,345                      ART UNIT: 1636  
ISSUE DATE: June 10, 2003                      EXAMINER: Ketter, James S.  
TITLE: Tissue Regenerative Composition, Method of Making, and Method of Use  
Thereof

Mail Stop 4  
Certificate of Correction Branch  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REQUEST FOR A CERTIFICATE OF CORRECTION UNDER 37 C.F.R. § 1.322**

The Assignee of record for the above-referenced patent, ACell, Inc., by virtue of an assignment document recorded on October November 27, 2000 at Reel/Frame 011318/0660, hereby requests that a Certificate of Correction be issued for U.S. Patent No. 6,576,265 B1 under 35 U.S.C. § 254 and 37 C.F.R. § 1.322.

A Certificate of Correction (PTO/SB/44 form) is attached in duplicate correcting a clerical oversight to remove a particular paragraph in the specification. Assignee notes that in an Amendment and Response dated December 6, 2002, Applicant requested that on page 1, line 9, the paragraph below be deleted from the specification.

**“Statement Regarding Federally Sponsored Research**

This invention was supported under National Institutes of Health Grants, 1-R43-HL85 761-01, 1-R43-DC-04387-01, and 1-R43-DC-4387-02.”

A copy of the Amendment and Response dated December 6, 2002, with relevant portions highlighted, is attached under Tab 1.


Because what is sought to be corrected appears to result from mistakes on the part of the Patent Office, Assignee respectfully submits that no fee is due under 37 C.F.R § 1.322. However, if a fee is nevertheless due, please charge Attorney's Deposit Account No. 20-0531.

The Patent Office is invited to call the undersigned representative with any questions concerning this submission.

Respectfully submitted,

Date: July 30, 2003  
Reg. No. 44,244

Tel. No.: (617) 248-7044  
Fax No.: (617) 248-7100

  
Ronda P. Moore, D.V.M.  
Attorney for Applicants  
Testa, Hurwitz & Thibeault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 6,576,265 B1  
DATED : June 10, 2003  
INVENTORS : Spievack

It is certified that an error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

~~In the Specification~~

Column 1

Lines 12-16, please delete the following paragraph:

--~~/~~STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

This invention was supported under National Institutes of Health Grants, 1-R43-HL85 761-01, 1-R43-DC-04387-01, and 1-R43-DC-4387-02, --

*do not underline*

AUG 8 - 2003

MAILING ADDRESS OF SENDER: Patent Administrator PATENT NO.: 6,576,265  
Testa Hurwitz & Thibault, LLP  
High Street Tower  
125 High Street  
Boston, MA 02110  
(617) 248-7000

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 6,576,265  
DATED : June 10, 2003  
INVENTORS : Spievack

It is certified that an error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

Column 1

Lines 12-16, please delete the following paragraph

[STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

This invention was supported under National Institutes of Health Grants, 1-R43-HL85 761-01, 1-R43-DC-04387-01, and 1-R43-DC-4387-02.]

MAILING ADDRESS OF SENDER: Patent Administrator      PATENT NO.: 6,576,265  
Testa Hurwitz & Thibeault, LLP  
High Street Tower  
125 High Street  
Boston, MA 02110  
(617) 248-7000

Czelebit



RECEIVED

DEC 10 2002

TECH CENTER 1600/2

PATENT

Attorney Docket No. SPV-001  
(7931/2)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#13B  
Lita  
12/15/02

APPLICANT(S): Spievack  
SERIAL NO.: 09/691,345 GROUP NO.: 1636  
FILING DATE: October 18, 2000 EXAMINER: Ketter, J.  
TITLE: TISSUE REGENERATIVE COMPOSITION, METHOD OF MAKING,  
AND METHOD OF USE THEREOF

Commissioner for Patents  
Washington, D.C. 20231

AMENDMENT AND RESPONSE

Sir:

This paper is responsive to the Office Action in the above-referenced patent application mailed from the U.S. Patent Office on September 10, 2002. Applicant believes that no fees are due. Should Applicant be in error, please charge deposit account no. 20-0531.

Before examining the claims in this application, please enter the following amendments.

In the Specification:

Page 1, line 9, please delete:

"Statement Regarding Federally Sponsored Research

This invention was supported under National Institutes of Health Grants, 1-R43-HL85 761-01, 1-R43-DC-04387-01, and 1-R43-DC-4387-02."

In the Claims:

Please amend claims 12-14 as follows.

12. (Amended) A composition comprising:

devitalized mammalian epithelial basement membrane and submucosa, wherein said basement membrane and submucosa are delaminated from the cells of a mammalian epithelium.

B<sup>1</sup>  
13. (Amended) A method for manufacture of a devitalized tissue graft composition, comprising:

deepithelializing a mammalian epithelial tissue to form a devitalized tissue having an epithelial basement membrane; and,

abrading said devitalized tissue on an abluminal surface of said tissue to form a delaminated tissue, wherein the delaminated tissue remaining after abrading said tissue, comprises at least a portion of the epithelial basement membrane and said delaminated tissue comprising said basement membrane induces endogenous tissue restoration.

14. (Amended) The method of claim 13 wherein deepithelializing said mammalian tissue comprises placing said tissue in a deepithelializing solution comprising 1.0 N saline.

---

Please add new claims 31-42 as follows.

---

31. (New) A matrix for inducing repair of tissue in a mammal, comprising:

B<sup>2</sup>  
an isolated devitalized mammalian epithelial basement membrane wherein said basement membrane is derived from small intestine, and the tunica propria immediately subjacent to said basement membrane.

32. (New) The composition of claim 11 further comprising cells.

33. (New) The composition of claim 32 wherein said cells comprise cells from a cultured cell line.

34. (New) A method for inducing repair of diseased, defective or damaged tissue in a mammal, said method comprising:

providing to the defect site, a devitalized matrix comprising a mammalian epithelial basement membrane wherein said matrix induces repair of said tissue when placed in contact with said tissue.

35. (New) The method of claim 34 wherein said repair comprises induction of connective tissue repair and epithelial tissue repair at said tissue defect site.

36. (New) The method of claim 34 wherein the source of said epithelial basement membrane is the intestine.

37. (New) The method of claim 34 wherein the source of said epithelial basement membrane is the urinary bladder.

38. (New) The method of claim 13 wherein said epithelial tissue comprises intestine.

39. (New) The composition of claim 12 further comprising cells.

40. (New) The composition of claim 39 wherein said cells comprise cells from a cultured cell line.

41. (New) The matrix of claim 31 further comprising cells.

42. (New) The matrix of claim 41 wherein said cells comprise cells from a cultured cell line.

Please cancel claims 1-5, ~~7-10~~, and ~~18-30~~, without prejudice, to their introduction into this or a related application.

#### Status of the Claims

Claims 1-5 and 7-30 are pending in this application. Claims 11-17 are allowed. Claims 3, 29, and 30 are objected to as being based on a rejected claim. Claims 1, 2, 4, 5, 7-10, and 18-28 are provisionally rejected under the judicially-created doctrine of obviousness-type double-patenting.

Upon introduction of the claim amendments, claims 11-17 and 31-42 will be pending with claims 1-5, 7-10, and 18-30 being canceled, claims 12-14 being amended, and new claims 31-42 being introduced. No new matter is introduced. Support for new claims 31-42 may be found in the claims as originally-filed, and throughout the specification.

#### REMARKS

Claim 3, which depends from claim 1, and claims 29 and 30, which depend from claim 10, are objected to as being dependent on a rejected based claim but would be



allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. Applicant has canceled claims 1, 3, 10, 29, and 30 and introduced new claims 31-33 with the limitations suggested in the Office Action as being drawn to allowable subject matter.

Accordingly, new claim 31 claims the subject matter canceled in claim 3 with all of the limitations of canceled claim 1 from which claim 3 depends. New claim 32 claims the subject matter canceled in claim 3 with all of the limitations of canceled claim 10. Claim 33 depends from claim 32 and should be allowable for at least all of the reasons for which claim 32 is allowable.

Provisional Rejection of Claims under the Judicially-Created Doctrine of  
Obviousness-Type Double-Patenting

Claims 1, 2, 4, 5, 7-10, and 18-28 are provisionally rejected under the judicially-created doctrine of obviousness-type double-patenting as being unpatentable over claims 1, 5, 6, 11, and 13 of co-pending U.S.S.N. 09/691,590. Claims 1, 2, 4, 5, 7-10, and 18-28 are hereby canceled, without prejudice, to their entry into this or a related application. Applicants respectfully request withdrawal of the rejection and allowance of all remaining claims in due course.

Related Pending Applications

Applicant has filed related applications in the U.S. Patent Office, U.S.S.N. 10/280,678; U.S.S.N. 10/281,372; U.S.S.N. 10/280,158; U.S.S.N. 10/280,802; U.S.S.N. 10/280,818; U.S.S.N. 10/280,582; U.S.S.N. 10/280,430; U.S.S.N. 10/280,552; U.S.S.N. 10/280,935; and U.S.S.N. 10/281,035 all claiming priority to the instant application, U.S.S.N. 09/691,345 and claiming benefit of provisional application U.S.S.N. 60/171,733.

Amendment to the Specification

The specification is amended merely to correct the statement regarding federally-sponsored research.

Information Disclosure Statement

Applicant submits herewith a sixth Supplemental Information Disclosure Statement. Applicant would appreciate receiving an initialed copy of the PTO-1449 with the next Office Action.


**CONCLUSION**

Applicant believes that all objections and rejections of the pending claims are overcome and claims 11-17, and 31-42 are in condition for allowance. Should there be any remaining questions or concerns, the Examiner is urged to call the undersigned representative at (617) 248-7044.

Respectfully submitted,

Date: December 6, 2002  
Reg. No. 44,244

Tel. No.: (617) 248-7044  
Fax No.: (617) 248-7100

  
Ronda P. Moore, D.V.M.  
Attorney for Applicant  
Testa, Hurwitz, & Thibault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110

**MARKED COPY OF AMENDMENTS TO SPECIFICATION**

Page 1, line 9, delete the following paragraph:

**[Statement Regarding Federally Sponsored Research**

This invention was supported under National Institutes of Health Grants, 1-R43-HL85 761-01, 1-R43-DC-04387-01, and 1-R43-DC-4387-02.]

**MARKED COPY OF THE AMENDED CLAIMS**

12. (Amended) A composition, comprising:

devitalized mammalian epithelial basement membrane and submucosa, wherein said basement membrane and submucosa are delaminated from the cells of [an] a mammalian epithelium[ and tunica muscularis of a mammalian epithelial tissue].

13. (Amended) A method for manufacture of a tissue graft composition, comprising:

[soaking a mammalian epithelial tissue in a ]deepithelializing a mammalian epithelial tissue [solution] to form a devitalized tissue having an epithelial basement membrane; and,

abrading said devitalized tissue on an abluminal surface of said tissue to form a delaminated tissue, wherein the delaminated tissue remaining after abrading said tissue, comprises at least a portion of the epithelial basement membrane and said delaminated tissue comprising said basement membrane induces endogenous tissue restoration.

14. The method of claim 13 wherein deepithelializing said mammalian epithelial tissue comprises placing said tissue in a deepithelializing solution compris[es]ing 1.0 N saline.